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Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. 98N-1038

These comments are submitted on behalf of IBP, Inc., a slaughterer and processor of beef and pork products with slaughter and manufacturing operations throughout the United States and Canada. Sales of beef and pork products produced by IBP are worldwide. IBP appreciates the opportunity to comment on this proposed rule. Our comments are divided into two sections. The first deals with the general comment on revisions to existing labeling requirements as defined in 21 CFR Part 179. The second addresses specific answers to the 15 questions detailed in the Docket.

THE NEED FOR REVISONS TO EXISTING LABELING REQUIREMENTS

Labeling - Irradiation vs. Pasteurization

IBP urges FDA to allow alternate nomenclature for labeling of products treated with irradiation for the purpose of eliminating bacterial pathogens. We submit that terms such as "Electron Pasteurization", "Gamma Pasteurization", or "Cold Pasteurization" are of equal value, perhaps of even greater value, in accurately describing the process to which a meat-food product is subjected to low level (<7.5 kgy) treatments for reduction of bacterial pathogens. Pasteurization is a process specifically applied to food products with a stated outcome of reducing or eliminating bacterial presence in or on the product. Irradiation, on the other hand, is more commonly associated with a treatment that serves as a sterilizing process. For example, irradiation applied to meat-food products in the context of "reducing pathogens such as *E. coli 0157:H7*" is a pasteurization process, not a sterilization process. Thus, the term "Electron Pasteurized" (in the case of an E-Beam type of treatment), is far more descriptive, in terms of both process and desired or intended outcome.

The term "irradiation" intones negative connotation to many consumers, for many different reasons. Alternate labeling that is fully descriptive, such as "Electron Pasteurized", would in our opinion be less offensive, and would be of significant benefit in expansion of the use of this technology in the advancement of food safety for meat products. IBP submits that the use of the radura, coupled with the term "Electron Pasteurized" will satisfy the consumer's need for disclosure, is an accurate description of the process and treatment, and serves to avoid conjuring of unwarranted concerns by an uniformed consumer.

Labeling of Irradiated Ingredients

IBP believes FDA's existing requirements for not requiring labeling of individual ingredients that are irradiated should be maintained. First, this past practice, extensively used in the spice industry, has already set a precedent that would have a significant economic impact on that industry. More importantly, what would be

the impact on consumer confidence in products that they have been using for decades? We believe that the use of the term irradiation or pasteurization will be used on a voluntary basis for those firms that wish to use it as a marketing point of difference and that its mandated use on ingredients would have a severe negative impact.

Sunsetting Irradiation Statement

Just as with milk pasteurization, if irradiation becomes the norm for a certain class of products such as ground beef, then the use of the radura and the irradiation or pasteurization statement have outlived their usefulness and need to be eliminated. However, since it is impossible to predict when that acceptance will occur, provision should be made for the elimination of the requirement, without a specific date given. Again, IBP believes that the use of the term "treated with irradiation" coupled with the radura symbol will be used a marketing point of difference, and may be used voluntarily, regardless of mandated use.

RESPONSES TO 15 QUESTIONS

1. The current description could be improved by allowing for the more descriptive terms of "electron pasteurized" or "gamma pasteurized".
2. The current disclosure statement is alarming to the average consumer - if there is nothing to fear, then why is it labeled with the statement at all?
3. We believe that the current statement causes inappropriate anxiety as most consumers relate irradiation with radioactivity and the associated fears of atomic testing in White Sands, NM.
4. The current statement should be changed to read "(Electron or Gamma or X-ray) pasteurized to reduce harmful bacteria" .
5. The level of awareness and education of the consumer dictate the answer to both of these questions. Since ingredients do not currently require disclosure, they are already being "misled" to a certain extent, according to the thinking of some. By the same token, the use of the term irradiation without a qualifying description such as "to reduce harmful bacteria" may lead some to believe the treated product is sterile, leading to lax handling practices.
6. The absence of a disclosure statement on ingredients could be construed as misleading, however, it would be far more disruptive to change. We do not believe consumers would be misled by the addition of such a statement, but we do believe that it will create unnecessary confusion in the marketplace.
7. We believe that with a few exceptions, (Carrot Top market outside of Chicago and the marketing of irradiated strawberries in Florida), there is very little direct consumer experience with products labeled as irradiated. We believe this is supported by the diverse consumer comments cited in the Docket on the labeling requirements; if there was greater exposure and understanding, we believe there would be more consensus on labeling requirements.
8. We believe the current labeling requirements have a negative impact on the use of irradiation as there is no allowance of more descriptive terms such as "electron pasteurization" A larger deterrent to the widespread use of irradiation deals with the availability of approved packaging which we address separately following this section.
9. We do not believe the typical consumer understands the effect of irradiation on foods. Again, we believe that if there were general understanding, there would be less dissension about the use and labeling thereof.
10. Our belief is that the radura is not generally recognized.
11. Since the radura is not recognized, the meaning is not generally understood.
12. We do not believe the logo has any meaning due to its lack of recognition.
13. Provision should be made for the expiration of the labeling statement, though an exact date is still TBD.
14. Criteria to determine the expiration date should be based on consumer acceptability.
15. Evidence of consumer familiarity should be derived from scientific evidence of the food safety benefits, consumer acceptability data collected by recognized consumer researchers (e.g. Christine Bruhn – University of California, Davis) and purchasing patterns. There are certain issues that will never be acceptable to all persons. As such, we must rely on science-based impartiality, not emotion, to institute beneficial change and technological advancement.

Packaging

IBP submits that achievement of the food safety benefit of irradiation is seriously jeopardized because of a lack of approved packaging materials for meat products. It is unfortunate that the outcome from the long awaited approval for irradiation of meat will be further delay in product development and marketplace introduction because of unnecessary regulatory hurdles that impede or restrict use of traditional and widely used packaging materials. IBP urges FDA to apply fast track approval for packaging materials that are commonly used for meat products in commerce today.

IBP appreciates FDA's consideration of these comments.

Respectfully,

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